



PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

NIKOLAI I. AFANASENKO ET AL. (PCT)

SERIAL NO.: 08/646,213 GROUP: 3302

FILED: MAY 7, 1996 EXAMINER: J. CLARK

FOR: DEVICE FOR TREATMENT OF PATIENTS WITH DISTURBED
POSTURE AND MOTOR ACTIVITY

DECLARATION UNDER RULE 132

ATTN: BOX FEE AMENDMENT
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, LJUBOV VIKTOROVNA PARAMONOVA, declare that I am Head Physician of the Urban Rehabilitation Center for Disabled Children, Novgorod, since 1993; and

that the following clinical tests (EXHIBIT D) were conducted under my supervision:

EXHIBIT D

MEDICAL TESTIMONY

to treatment of child patients with ICP using a novel technique with the aid of the loading suit πK-92 "Adeli" at the Municipal Rehabilitation Treatment Center for Children, City of Nizhni Novgorod

Every year about two thousand child patients suffering from various pathologies pass through the Center, including 250-300 children with infantile cerebral paralysis.

The treatment technique using the therapeutic loading suit πK-92 "Adeli" has been utilized for treating the patients with ICP since March, 1995, after the specialists of our Center have passed through training in this treatment technique under the guidance of Prof. K.A. Semenova on the basis of the Kaluga Bor Preventorium.

From March to July, 1995, the suit was applied for treating 23 patients with ICP, aged from 11 to 16, of whom ten patients with spastic diplegia, eight patients with the hemiparetic form, three patients with the atonic-astatic form, and two patients with hyperkinetic form.

The patients were selected with strict amount of indications and contraindications for use of the present treatment technique.

The treatment course lasted 20 days, with daily session of from one hour and a half to two hours. Each of the patients was given a single treatment course.

The therapeutic suit "Adeli" was used in combination with other procedures and techniques commonly adopted for treating ICP, that is, massage, therapeutic exercise, physiotherapy reflexotherapy, logopedic exercises, studies with a teacher, and medicinal correction. The treatment efficiency was assessed clinically.

The result obtained from the ambulant use of the therapeutic loading suit were as follows: an improvement was noted in 83% of the cases, whereas the efficiency of treatment without applying the new technique was 70-73%.

The best results were obtained from the treatment of the patients with spastic diplegia, hemiparetic, and hyperkinetic ICP forms.

Virtually all the patients with spastic ICP forms exhibited an increased extent of voluntary motions. The extent of active and passive movements in the joints increased by 5-10 degrees. The gait was improved, that is, correct pace movements were formed, the pace length is increased, and the sagittal and frontal trunk rocking motion while walking was reduced.

Coordination of movements was improved, and voluntary motions became less sweeping. The hyperkinetic ICP patients exhibited not only a reduced amount of hyperkinesis but also a less pronounced speech disturbances. An emotional status of the patients was much improved.

At present, we have acquired four such suits for children of 3 to 5 years old. In September and October of the instant year, a total of 17 child patients were admitted for treatment at the Center, of whom one patient has learned walking, two patients

standing, and one patient, sitting without attendance. The treatment of one patient was ineffective.

The rest of the patients treated developed correct pace movements and exhibited an increased extent of motions in the joints of the limbs, a reduced myogenic tonus, and an improved coordination of movements.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 12. 02. 98.



Name: LJUBOV VIKTOROVNA PARAMONOVA
Title: Head Physician